

Pharmacy Consultation Guide

The following Guide has been created as a useful tool to help determine whether your patient is suitable for Viaredin, or whether he should visit a doctor for further advice. Use of the Pharmacy Consultation Guide is optional. Primarily you should rely on your professional judgement to decide when and how to use it. The Essential Information for the Supply of Viaredin provides additional background information.

Repeat supply

If the patient has previously taken Viaredin, he should be asked if anything has changed with respect to his health status or use of concomitant medication. There is no need to repeat the questions below prior to resupply in that case. Please remind the patient to make an appointment with his doctor as soon as possible within the first 6 months after starting to use Viaredin, to ensure that his erection problems are not caused by any serious health condition. If any factors have changed, Sections 2–4 should be reviewed again. The repeat supply tear-off slip (see below) can also be given to the patient.

1. Who is Viaredin for?

Viaredin is only indicated for men aged 18 years and older with erectile dysfunction (ED) (i.e. difficulty in getting and/or maintaining an erection satisfactory for sexual performance). This product must not be supplied to men without ED. It is not essential whether a patient has a previous diagnosis of ED.

It is important to detect if a patient is already receiving treatment for this condition.

Patients currently prescribed sildenafil 50 mg can be supplied with this product if they meet the criteria for pharmacy supply, provided they do not take more than 50 mg daily. If a patient is using a different dose of sildenafil or another ED treatment, he should be referred to his doctor.

2. Check patient's cardiovascular (CV) status

If the patient answers **YES** to any of the following: **do not supply the product** and refer to the doctor. If you have any reason to suspect, based on physical status, the patient should not use this product, refer to the doctor too.

- Y** **N** Has your doctor advised that you are not fit enough for any physical and/or sexual activity?
- Y** **N** Do you feel very breathless or experience chest pain with light or moderate physical activity, such as walking briskly for 20 minutes or climbing two flights of stairs?
- Y** **N** Have you had a heart attack or a stroke within the last 6 months?
- Y** **N** Do you have any other heart problems or do you receive any treatment for any of the following:
- Unstable angina (chest pain), irregular heartbeat or palpitations (arrhythmia)
 - Low blood pressure or uncontrolled high blood pressure
 - A problem with one of the valves in your heart (valvular heart disease)
 - A problem where the heart muscle becomes inflamed and does not work as well as it should (cardiomyopathy)
 - Heart problems causing blood flow issues (e.g. left ventricular outflow obstruction, aortic narrowing) or severe cardiac failure

3. Check concomitant conditions

If the patient answers **YES** to any of the following: **do not supply the product** and refer to the doctor.

- Y** **N** Do you have Peyronie's disease or any other deformation of the penis?
- Y** **N** Have you ever had loss of vision because of damage to the optic nerve (such as non-arteritic anterior ischaemic optic neuropathy [NAION]) or an inherited eye disease (such as retinitis pigmentosa)?
- Y** **N** Do you have any bleeding issues (e.g. haemophilia) or active stomach ulcer?
- Y** **N** Do you have previously diagnosed hepatic (liver) disease (including cirrhosis of the liver) or severe renal (kidney) impairment?
- Y** **N** Do you have any of the following: sickle cell anaemia, multiple myeloma or leukaemia?
- Y** **N** Do you have galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption?

4. Check concomitant medication use

If the patient answers **YES** to any of the following or if there is uncertainty around the patient's current medications: **do not supply the product** and refer to the doctor.

- Y** **N** Are you taking nitrates (nicorandil or other nitric oxide donors e.g. glyceryl trinitrate, isosorbide mononitrate or isosorbide dinitrate) for chest pain?
- Y** **N** Are you using riociguat or other guanylate cyclase stimulators for lung problems?
- Y** **N** Are you taking drugs called 'poppers' for recreational purposes (e.g. amyl nitrite)?
- Y** **N** Are you taking ritonavir (for HIV infection)?
- Y** **N** Are you taking any CYP3A4 inhibitors, e.g. saquinavir (to treat HIV infection), cimetidine (a heartburn treatment), itraconazole or ketoconazole (to treat fungal infections), erythromycin (antibiotics) or diltiazem (for high blood pressure)?
- Y** **N** Are you taking any alpha-blockers, such as alfuzosin, doxazosin or tamsulosin (to treat urinary problems) due to enlarged prostate (benign prostatic hyperplasia) or occasionally to treat high blood pressure?

Additional advice

1. As well as the physical causes of ED (e.g. diabetes mellitus cardiovascular disease) you should also consider psychological causes, such as undiagnosed anxiety, depression, or excessive alcohol use.
2. The following medications can cause ED: diuretics, anti-hypertensives, corticosteroids, anticonvulsants and recreational drugs.
3. Besides, you should provide lifestyle advice and recommend a follow-up with a doctor.

Dear Doctor,

Please can you advise this patient in relation to erectile dysfunction. We had a discussion in the pharmacy about his suitability for supply with Viaredin due to his cardiovascular health/concomitant medicines /other condition:

**PHARMACY
STAMP**

Please keep this slip and present to the Pharmacist when you next intend to purchase Viaredin.

**PHARMACY
STAMP**

Before re-supply your Pharmacist will assess your health condition to ensure that there have been no changes in your health or medications.

Pharmacist signature:..... Date:.....

Pharmacist signature:..... Date:.....

Points for counselling and additional information

Please follow these points to ensure that your patient is counselled appropriately whether he is supplied the product or not.

Advice for men who have not been supplied Viaredin

Men who have not been supplied Viaredin due to their cardiovascular health or another concern must be told to see their GP as soon as they can within 6 months. The tear-off slip (below) can be filled in and given to the man to facilitate his discussion with the doctor.

Advice for men who have been supplied Viaredin

Men should be advised:

- They should schedule a health check-up with their GP as soon as possible within the first 6 months of starting to use Viaredin to ensure that their erection problems are not caused by any serious health condition.
- Viaredin is only indicated for men aged 18 years and older who have erectile dysfunction (ED). Men who without ED will not benefit from using this product.
- The maximum recommended dosing frequency is one 50 mg tablet per day.
- Take one tablet approximately 1 hour prior to a sexual intercourse. Viaredin starts to work within 30 minutes.
- Take with or without food. Please consider that Viaredin may take longer to work after a high-fat meal.
- They may need to take Viaredin a number of times on different occasions (a maximum of one 50 mg tablet per day), before they can achieve a penile erection satisfactory for sexual activity. If, after several attempts, patients are still not able to achieve a penile erection sufficient for satisfactory sexual activity, they should be advised to consult a doctor.
- Medicines containing any nitrates (e.g. glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate, amyl nitrite also known as 'poppers'), or nitric oxide donors (e.g. sodium nitroprusside or nicorandil), must NOT be used at the same time as Viaredin as this combination may lead to a dangerous fall in blood pressure.
- Do not take Viaredin with grapefruit or grapefruit juice, as it may modestly increase plasma levels of sildenafil.
- Men should tell their doctor that they have started taking Viaredin, especially if they receive any new medicines.
- Remind patients about common side effects. These include: headache, dizziness, flushing, dyspepsia, nasal congestion, nausea, visual disturbance, cyanopsia (blue-tinted vision) and blurred vision.

Note: If any of these become a concern, advise the patient to consult a pharmacist or a doctor.

Men should be advised to STOP TAKING Viaredin and seek medical advice IMMEDIATELY if they experience the following SERIOUS SIDE EFFECTS (side effects can be reported by patients or pharmacists via the respective CA website):

- Chest pains: If this occurs before, during or after intercourse, they should get into a semi-sitting position and try to relax. Nitrates must NOT be used to treat chest pains.
- An allergic reaction. Symptoms include sudden wheeziness, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat.
- A sudden decrease or loss of vision.
- A persistent and sometimes painful erection lasting longer than 4 hours.
- Serious skin reactions such as Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Syndrome (TEN). Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits.

Follow up advice for all men

- ED can be associated with a number of contributing conditions, e.g. diabetes mellitus, hypertension, hypercholesterolaemia or cardiovascular disease. As a result, all men with ED should be advised to consult their doctor within 6 months for a clinical review of potential risk factors associated with ED.
- You may also want to check if the man is buying products from unregulated sources. It is important to explain that these products are not tested for their safety or effectiveness, may not contain the ingredients listed within them and are therefore potentially dangerous, unlike products sourced from a pharmacy and medicines obtained via prescription from the doctor.
- Provide appropriate advice on lifestyle factors and general healthy living, including:
 - Losing weight
 - Cutting back on alcohol/recreational drugs
 - Giving up smoking
 - Exercising regularly
 - Reducing stress
- You can also offer the man a health check, if available.

Your pharmacist has supplied you with Viaredin today for your personal use.

Please make an appointment to see your GP as soon as you can within 6 months of the date of first receiving Viaredin (see date on reverse) to check for underlying medical problems that can sometimes be associated with erectile dysfunction.

You have not been provided with Viaredin for ED today as it may not be suitable for you to take it without consulting your doctor.

You should discuss with your doctor other suitable options. Therefore, please make an appointment to see your GP as soon as you can within the next 6 months and present this slip.